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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/382,794	08/25/1999	ANATOLY DRITSCHILO	010091-041	5682

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EXAMINER	
FISHER, ABIGAIL L	
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1616	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/382,794	DRITSCHILO ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-37,39,41,43,44 and 71-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/19/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Receipt of Request for Continued Examination and Amendments/Remarks filed on March 19 2008 is acknowledged. Claims 1-33, 38, 40, 42 and 45-70 were/stand cancelled. Claim 34 and 71 were amended. Claims 72 and 73 were added. Claims 34-37, 39, 41, 43-44, 71-73 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 19 2008 was considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-37, 39, 41, 43-44, and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claim 34 has been amended to recite the limitation "freestanding retention therein indefinitely" in the reply filed on June 6 29 2007. This recitation is considered new matter. The applicant has not indicated where support for this amendment can be found. Additionally, the examiner cannot ascertain where support for this amendment can be found.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-37, 39, 41, 43-44, and 71-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claims 34 and 71 is a relative term which renders the claim indefinite. The term "substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since applicant has not provided a definition of substantially, it is unclear what is meant by the term "substantially hollow". Is 90% hollow substantially hollow?

Claims 34 and 71 as currently written are vague and indefinite. Claims 34 and 71 can be reasonably interpreted two different ways. The claims can be interpreted as

a device consisting of a hollow seed and a therapeutic agent. Alternatively as the claim is written, the claim indicates that the hollow seed is arranged "to provide for" the controlled diffusion of a therapeutic agent. The language "to provide for" indicates that seed is capable for controlled release of a therapeutic agent, or an intended use of the seed, however the therapeutic agent is not necessarily present.

For the purposes of applying art, both interpretations of the claims will be utilized.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34, 36, and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Merriam-Webster International Dictionary (1963).

Since one interpretation of the claims are where the therapeutic agent is not present. The instant claims are directed to a hollow seed made of metal.

Merriam-Webster International Dictionary indicates a seed (definition 4b) is a small usually glass and gold or platinum capsule used as a container for a radioactive substance to be applied usually interstitially in the treatment of cancer. Since it is a container, it is inherently hollow (i.e. it has a cavity). Both gold and platinum are metals. It is noted that Applicant has previously provided the same definition for a seed in the response filed on March 19 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34-37, 39, 41, 43-44, and 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rashid (GB 2243777, PTO Form 1449) in view of Sioshansi et al. (US Patent No. 6030333).

Applicant Claims

Applicant claims a device consisting of a hollow seed and a therapeutic agent comprising a radionuclide and a nucleic acid sequence or a protein or polypeptide.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Rashid is directed to a device for implantation comprising a chamber containing an active ingredient which is released through a capillary bore abstract). The device is constructed from a **cylindrical** tube containing the active ingredient (page 2, last two sentences). The length of the device is from 5 to 100 mm (0.2 to 3.9 in) with an external diameter of 1 to 40 mm (0.04 to 1.6 in) (page 3, 1-4). The internal diameter is from 0.1 to 10 mm (0.004 to 0.4 in) (page 4, line 7-8). If required, the open end of the capillary tube may be provided with a copy which dissolves away on administration, for example formed from a sugar or gelatin (page 5, second paragraph). Figure 1 indicates that each end is sealed with a water soluble sugar end cap (page 9, Fig 1 description). It is disclosed that the device can be formed of a plastics material, a ceramic material, a metal such as stainless steel, or glass. (page 3, lines 4-6). Suitable ceramic materials include **titanium** or its alloys (page 3 line 22). It is disclosed the invention is intended for subcutaneous implantation, insertion into body cavities and may also be used for oral administration (page 5, second paragraph). The active ingredient may be a medicament, a contraceptive, or for prophylactic, diagnostic or nutritional use (page 5, last paragraph). Various different actives are listed (page 6-7).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Rashid does not specify that the active agents are a radionuclide and a nucleic acid sequence, protein, or polypeptide. However, this deficiency is cured by Sioshansi et al.

Sioshansi et al. is directed to implantable radiotherapy device. It is disclosed that for radiation therapy that a patient is exposed from an external beam or that the radioactivity may be incorporated into an implantable device (column 1, lines 36-40). Seeds which are utilized to implant the radioactivity are implanted individually at a treatment site within and/or around a lesion (column 1, line lines 61-65). These seeds when as radiotherapy devices are discrete, or point, sources of radiation (column 1, lines 67). It is disclosed that in order to deliver both radiation and non-radiation treatments together it may be desirable to apply one more non-radioactive therapeutic agents. Therapeutic agents for example biological agents such as proteins and growth factors can be included (column 11, lines 56-63). The radiation therapy includes radionuclides such as ^{45}Ca, ^{123}Sn, ^{89}Sr, ^{32}P, ^{33}P, ^{103}Pd, and ^{123}I (column 12, lines 57-61).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Rashid and Sioshansi et al. and utilize a radionuclide and a protein as the active agent. One of ordinary skill in the art would have been motivated to utilize a radionuclide and a protein because it is taught in the art that this type of combination is useful in various therapies as taught by Sioshansi et al. Further more, the selection of a specify drug is considered prima facie obvious depending on the desired condition/symptoms to be treated.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Regarding the limitation of the seed having openings at each end, the ends of the invention of Rashid are open. During the formation they may be capped, if required. However, even if they are capped, once they are implanted, the cap dissolves therefore at that point the cap no longer exists and the opening are completely open.

Regarding the claimed dimensions of the seed, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5]**

Claims 34-37, 39, 41, 43-44 and 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coniglione (US Patent No. 5713828, PTO Form 1449) in view of Sioshansi et al.

Applicant Claims

Applicant claims a device consisting of a hollow seed and a therapeutic agent comprising a radionuclide and a nucleic acid sequence or a protein or polypeptide.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Coniglione is directed to a hollow tube brachytherapy device. The device is utilized for the utilized for the interstitial radiotherapy of malignant neoplasm and other

diseases treatable with radiation (column 4, lines 18-20). The hollow tubular support is open on both ends (column 4, lines 21-22). The hollow tube design of the device permits the growth of tissue into the device. The tissue growth acts to anchor the device at the application site and minimize the potential for migration (column 5, lines 48-51). Suitable radioisotopes utilized are palladium-103 and iodine-125 (column 6, line 2-3). The hollow tube shaped seed substrate may be made of titanium or other biocompatible metal (column 10, lines 60-61). The tubular sections of the titanium are made that are 4.5 mm (0.18 in), outside diameter of 0.57 mm (0.0224 in), and inside diameter of 0.5 mm (0.0197 in) (column 11, lines 1-2). This corresponds to a wall thickness of 0.0027 in.

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Coniglione does specify the incorporation of a nucleic acid, protein, or polypeptide. However, this deficiency is cured by Sioshansi et al.

Sioshansi et al. is directed to implantable radiotherapy device. It is disclosed that in order to deliver both radiation and non-radiation treatments together it may be desirable to apply one or more non-radioactive therapeutic agents. Therapeutic agents for example biological agents such as proteins and growth factors can be included (column 11, lines 56-63).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Coniglione and Sioshansi et al. and utilize a protein as an additional active

agent. One of ordinary skill in the art would have been motivated to utilize a radionuclide and a protein because it is taught in the art that this type of combination is useful in various therapies as taught by Sioshansi et al. Further more, the selection of a specify drug is considered prima facie obvious depending on the desired condition/symptoms to be treated.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner
Art Unit 1616